

**Regulatory Impact Assessment of the
EU White Paper:
Strategy for a Future Chemicals Policy**

**Final Report
(Contract Reference 16/13/33)**

Prepared for

**The Department of the Environment,
Transport and the Regions**

By

Risk & Policy Analysts Ltd

May 2001

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EXECUTIVE SUMMARY

On 27 February 2001, the European Commission published a White Paper on its Strategy for a Future Chemicals Policy. The UK Government believes that the White Paper is likely to result in legislation which will have major implications for UK authorities and for business. Risk & Policy Analysts Ltd has therefore been commissioned to conduct a Partial Regulatory Impact Assessment (RIA) of the White Paper. The aim of this partial RIA is to:

- identify the potential costs (including costs to SMEs) and benefits for the UK of the proposals in the EU White Paper and of alternative options including non-legislative ones; and
- to inform the UK position for negotiations of Council Conclusions on the White Paper.

Three different scenarios were considered in order to fully understand the implications of the EU White Paper. The first of these acts as the baseline for the analysis, and reflects the existing legislative process together with voluntary commitments already made by industry. The second scenario reflects the requirements of the UK Chemicals Strategy (DETR, 1999), while the third scenario represents requirements under the EU Strategy as set out in the White Paper (although a number of assumptions have had to be made as to how the White Paper provisions would be implemented in practice).

The key findings of the partial RIA are that there are considerable differences in interpretation of the White Paper requirements and their implications between different organisations consulted for this RIA. This has introduced uncertainty into the analysis findings.

Compared to the Base scenario, the UK Chemicals Strategy and the EU White Paper scenarios have the potential to realise a range of benefits associated with reduction in the risks of chemicals arising from the provision of additional information, leading to earlier restrictions on substances of concern. The potential maximum benefits could include:

- reduced costs of occupational injuries and fatalities amounting to £64-129 million over 10 years;
- reduced costs of occupational asthma and dermatitis totalling £580 million to £1.2 billion over 10 years; and
- unknown benefits arising from reduced costs associated with occupational cancer, non-occupational exposure and environmental damage associated with chemicals.

In practice, it is unlikely that any of the scenarios would result in reduction to zero of occupational ill-health and death related to chemicals; the actual benefits will therefore be lower than these levels. However, to any reductions in occupational ill-health must be added benefits arising from reductions in health effects to the general public and reductions in chemical related environmental damages. It has not proved possible within

this RIA to place values on the potential magnitude of such benefits, nor on the relative benefits that each scenario would provide.

Additional benefits will arise to the chemical industry from the increased threshold for notification of new substances proposed by the EU White Paper. This is estimated at £34 million in present value terms (at 6% over the 20 years). These benefits may be particularly important to SMEs, which are significant generators of new chemicals. Consultation with industry has indicated that the increased threshold for notification of new substances may also result in more new substances being brought to market, with consequent benefits for industry and for users of chemicals.

The best estimates of the total present value costs of each of the scenarios are as follows (at a 6% discount rate over 20 years):

Base Legislation:	£107 million
UK Chemicals Strategy:	£197 million
EU White Paper:	£620 million

The EU White Paper results in additional costs of around £513 million over the Base Legislation scenario and £423 million over the UK Chemicals Strategy. These are costs to the UK alone. It should be noted that these estimates depend upon a range of assumptions about how each of the scenarios will operate in practice and are therefore subject to some uncertainty. Sensitivity analysis suggests that changes in assumptions concerning the costs of testing could add as much as £100 million to the estimates for the EU White Paper, as could assumptions raising the share of chemicals falling to UK industry from 12% to 20%.

Comparing the potential costs and benefits of the different scenarios is difficult, particularly as any such comparison should include the costs arising as a result of associated risk reduction requirements. Because it is not possible to judge what types of risk reduction may occur in reality, no costs can be placed on this part of the equation.

Making a simplistic comparison of the estimated costs and benefits outlined above indicates that the additional costs associated with the UK Chemicals Strategy (excluding those of any risk reduction measures) are likely to be justified if it results in the reduction of around 15% of the cases of occupational asthma and dermatitis occurring in the UK. This compares with the current HSE target of a 20% reduction in work-related ill-health as a whole. Further reductions in health effects across both worker populations and the general public together with environmental benefits and greater public confidence would increase the justification. The case may be more marginal for the EU White Paper, however, with a 70% reduction in cases of occupational asthma and dermatitis (a highly optimistic assumption) being required to offset the estimated costs.

Under the Base Legislation scenario, Government in the form of the Competent Authorities is predicted as bearing 12% of the total costs. This reduces to 9% under the UK Chemicals Strategy, as industry picks up a greater share of responsibility. However, the transfer of costs is more dramatic under the EU White Paper, with Competent Authorities bearing only 1% of total present value costs. Of particular concern with the latter scenario, though, is the impact that it may have on SMEs as they are likely to

constitute a higher proportion of the downstream users affected (who are predicted as incurring costs of around £44 million under this scenario). The proportion of existing chemicals produced by SMEs, and thus their share of the cost burden with regard to testing and authorisation, is unknown. However, a significant proportion of the specialty chemicals falling under the requirements of the White Paper will be produced by SMEs.

There are likely to be significant compliance issues under the EU White Paper requirements (although the detailed implementation has yet to be determined). In particular, there are questions over the ability of manufacturers to meet the full testing, risk assessment and risk management requirements within the time frame allowed. This is a particular concern for SMEs. There are also questions over the sharing of testing and risk assessment responsibilities between companies, given concerns over commercial confidentiality.

It is also unclear how the registration, data collection and testing activities required of downstream users can be enforced, particularly in light of the problems which have risen under the Existing Substances Regulation. For example, there are questions over what regulatory authorities will have responsibility for ensuring that a chemical is registered and assessed, and that all uses (envisaged and non-envisaged) have been assessed as required. Furthermore, issues arise over enforcement of the requirements on importers of chemicals to the EU.

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1. INTRODUCTION

1.1 Background

On 27 February 2001, the European Commission published a White Paper on its Strategy for a Future Chemicals Policy (European Commission, 2001). This Strategy proposes that new and existing substances be subject to a single system of control from 2012.

There would be data requirements¹ for all substances produced at over 1 tonne per annum (tpa), raising the current threshold for new substances. Increasing levels of data would be required according to the quantities produced. The new system would involve the following key stages:

- *registration* by industry of basic information for all substances (existing and new) exceeding a production volume of 1 tonne per annum (tpa);
- *evaluation* by the authorities of substances exceeding a production volume of 100 tpa and those of lower tonnage where there exists a concern, leading to testing programmes where appropriate; and
- *authorisation* by the authorities of substances with properties that give rise to very high concern, where specific permission will have to be given before such a substances can be used for a particular purpose, marketed as such or as a component of a product.

The new system would place an increased responsibility upon industry to provide data on substances, in particular existing substances. It advocates the provision of earlier and more comprehensive information on substances to downstream users. Moreover, it would place a requirement upon downstream users to notify the authorities of uses not originally envisaged by the manufacturer ('unintentional' uses) and to undertake assessments of the risks associated with those uses on the direction of the authorities.

1.2 The Chemicals Industry

1.2.1 The EU Chemicals Industry

There are over 100,000 chemicals registered in the European Union (of which around 90% are estimated to be currently on the market). Around 30,000 of these are marketed in quantities of over 1 tpa and 10,000 in quantities over 10 tpa. Around 2,500 of these chemicals are produced in quantities of over 1,000 tpa (so called High Production Volume, HPV, chemicals).

EU chemical production accounted for around €403 billion in 1999 or about 29% of global production (CEFIC, 2000). Roughly 34,000 companies make up the EU

¹ On physicochemical properties, toxicological and ecotoxicological effects, exposure, etc.

chemicals industry, with 96% being small and medium-sized enterprises (SMEs)², accounting for 28% of sales. The remaining 4% of (larger) companies generate 72% of total sales (CEFIC, 2000).

1.2.2 The UK Chemicals Industry

Table 1.1 provides details of the UK chemicals manufacturing industry. The industry is also important to downstream users of chemicals, as discussed below.

Table 1.1: The UK Chemicals Industry (2000)	
Gross output (all products including merchandising)	£49 billion (10% of UK manufacturing)
Sales (chemicals and chemical products)	£34.3 billion (12% of EU)
Exports	£25.7 billion
Imports	£21.4 billion
Trade surplus	£4.3 billion
Employment	251,000
UK capital investment	£2.7 billion
R&D expenditure (1999)	£3.3 billion
Output growth in 2000	4.6%
Forecast output growth in 2001	3 - 3.25%
Average annual output growth in 1990 to 2000	3%
Source: Chemical Industries Association	

There are various industries that use chemicals, both in the manufacture of other products and directly. Table 1.2 provides an indication of the number of companies involved, the number of chemicals used and the numbers of small and medium sized enterprises in selected sectors.

1.3 Approach to the RIA

The UK Government believes that the White Paper is likely to result in legislation that will have major implications for the UK authorities. The chemicals and downstream industry also claims that the proposed strategy will have severe impacts on their competitiveness and upon innovation. In addition, there is concern that the strategy could have a disproportionate impact on small and medium sized enterprises.

² Defined as enterprises with below 250 employees/€40 million turnover, in line with EU definitions.

Sector	No of Companies	No of SMEs	No of Chemicals
Rubber manufacture	600 - 800	540 - 720 (90%)	300
Man-made fibres		65	
Coating		2,000	
Plastics and rubber ¹		6,000	
Dyes and pigments		40	
Aerosols		150	
Printing inks		120	
Surface treatment	600 - 800	300 - 400 ²	300 - 400

¹ This figure is likely to include some of those companies under rubber manufacture.
² Companies with fewer than 10 employees (based on data from the Metal Finishing Association).

The Government believes that the impact of proposals for EU legislation on jobs, business, the voluntary sector, the citizen and the environment should be assessed. To assist consideration of such proposals, the Government prepares Regulatory Impact Assessments (RIAs).

This partial RIA is intended to inform the Government’s position on the White Paper. It has, therefore, been necessary to complete the project in a relatively short period of time, in order to gauge the potential magnitude of the impacts in advance of upcoming discussions. Further details on issues that this RIA address and the objectives of the RIA are given in Section 2.

The RIA draws upon a review of relevant literature. However, the majority of information is based upon discussions held with UK Government departments responsible for administering various aspects of the current system (and which would also have responsibilities under the new Strategy), with companies and trade associations representing manufacturers of chemicals and with a selection of trade associations representing downstream users of chemicals. A list of organisations contacted is provided in Annex 1, while the questions asked of them are provided in Annex 2.

In undertaking the assessment, three policy scenarios have been compared: the current situation, the UK Chemicals Strategy (in the process of being implemented) and the strategy proposed in the EU White Paper. These scenarios are described further in Section 3.

Section 4 then sets out the types of benefits that may arise from the strategy set out in the EU White Paper, contrasting these to the other two scenarios. Cost estimates have also been developed for the three scenarios (see Section 5), by breaking them down into their key components.

Sensitivity analysis has been undertaken on a number of the assumptions underlying the cost estimates. This includes estimates of the costs associated with the testing requirements as these vary across sources. In addition, different assumptions as to the number of chemicals that will need to be assessed by UK industry under each of the three scenarios have been examined. The conclusions drawn from this sensitivity testing are reported in the Section 5.

The issues raised by industry consultees with regard to the introduction of the proposed EU strategy are set out in Section 6, followed by a summary of potential compliance issues in Section 7. Our overall conclusions are then summarised in Section 8.

2. THE ISSUE AND OBJECTIVE

2.1 Reasons for Development of an EU Chemicals Strategy

The key reason for the European Commission's decision to develop a chemicals strategy is concern over the adequacy of the current system of controls over chemicals and, thus, the ability to address the associated risks to health and the environment. In particular, there is concern that legislative action to restrict the use of harmful chemicals takes too long before yielding a result.

Such concerns were debated at the informal Council of Environment Ministers in Chester in April 1998. As a result of the debate, the Commission undertook a review of four key legal instruments governing chemicals in the Community³. The review identified a number of major problems with the current system of controls, in particular:

- the lack of testing and risk assessment requirements for existing substances, which amount to 99% of the total volume of substances on the market;
- the general lack of knowledge about the properties and uses of existing substances;
- the slowness and resource-intensive nature of the current risk assessment system for existing substances; and
- the inappropriate allocation of responsibility for risk assessment of existing substances between public authorities and industry, and between manufacturers and downstream users.

The review also concluded that current liability regimes were insufficient to remedy these problems because the need to prove a causal link between a substance and resulting damage is often virtually impossible, given the lack of test data and the separation of cause and effect over time. The EU Strategy aims to address this issue, by ensuring that a wider range of data on the potential risks arising from chemicals is available to authorities and the public.

2.2 Objectives of the Strategy

The key risks that the Strategy is designed to address concern the potential impacts of chemicals on human health and the environment. The White Paper identifies as potential risk areas:

³ Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances, as amended; Directive 88/379/EEC relating to the classification, packaging and labelling of dangerous preparations; Council Regulation (EEC) 793/93 on evaluation and control of risks of existing substances; and Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations.

- ‘justified concern’ that certain chemicals play a causative role in diseases, such as testicular cancer and allergies, the incidence of which has increased significantly over recent decades; and
- reported links between reproductive and developmental effects and endocrine substances in wildlife populations that have led the Commission’s Scientific Committee on Toxicity, Ecotoxicity and the Environment to conclude that there is a potential global problem. This concern is based on recent findings of high levels of persistent potential endocrine disrupting chemicals in several mammalian species in oceanic waters.

The objectives of the proposed EU Chemicals Strategy, as described in the White Paper, are:

- protection of human health and the environment;
- maintenance and enhancement of the competitiveness of the EU chemical industry;
- prevention of fragmentation of the internal market;
- increased transparency, by providing access to information on chemicals to consumers;
- integration with international efforts on chemical safety;
- promotion of non-animal testing; and
- conformity with EU international obligations under the WTO regarding barriers to trade and discrimination against imported substances and products.

2.3 Objectives of the RIA

Although much of the detail of how the strategy proposed in the EU White Paper will be implemented has yet to be defined and agreed, the proposals as they stand may have far-reaching implications for both UK authorities, the UK chemicals industry and associated industrial users of chemicals.

As a result, the DETR has commissioned this partial regulatory impact assessment (RIA) to inform the UK Government’s input into the development of the EU strategy. The objectives of the partial RIA are:

- to identify the potential costs (including the costs for SMEs) and benefits for the UK of the proposals in the EU White Paper and of alternative policy scenarios, including non-legislative ones; and
- to inform the UK position for negotiations of Council Conclusions on the White Paper.

To achieve these objectives, the RIA needs to consider the risks, benefits, costs and compliance issues surrounding the regulatory and non-regulatory options.

3. IDENTIFICATION OF OPTIONS

3.1 Introduction

The White Paper proposes changes to the way that chemicals are regulated at the policy level. It is, therefore, appropriate to base the comparison upon alternative options that are also at the policy level. In order to provide a baseline against which the EU proposals can be compared, the current regulatory regime for control of chemicals has been considered as one option (referred to as the Base Legislation scenario). The third policy option reflects the regime currently under development in the UK: the UK Chemicals Strategy.

These three options were chosen following discussions involving a number of UK Government departments since they are the most likely scenarios under which chemicals will be controlled in the UK in the future.

The following sections provide a summary of the main elements of the three scenarios as considered for this RIA, in terms of the main legislative controls upon manufacture and use of chemicals. Tables 3.1 to 3.4 (given at the end of this section) provide a summary of the key assumptions underlying each of these options. The tables also set out the assumptions that have been made when predicting the impacts under the different scenarios over time (taking a 20 year time horizon running from 2001 to 2020).

The list of legislative controls and associated activities is not exhaustive and only includes those aspects where significant differences are likely to arise across the scenarios. Other legislative and non-legislative controls upon chemicals are described in Section 3.2.4.

In order to provide a basis for comparison of the costs and benefits of the three scenarios, their key elements have been separated into the three main aspects of the White Paper strategy (registration, evaluation and authorisation). In addition, the requirements for testing of substances have also been included separately when developing cost estimates to enable a better comparison between the scenarios. Although the procedures are not entirely equivalent, it is considered that this is the most appropriate basis for comparison of the costs and benefits (Sections 4 and 5).

3.2 Key Elements of the Scenarios

3.2.1 Base Legislation Scenario

This scenario is aimed at reflect the legislative requirements and voluntary programmes that are currently in place for both new and existing substances. It does not, however, include any of the developments or activities that are expected to take place under the UK Chemicals Strategy.

New Substances

New substances⁴ placed on the market are required to be notified to the Competent Authority, with data provided according to the quantity marketed. These data range from basic information on the properties of a substance to detailed information on its health and environmental toxicity. A risk assessment is also required to be submitted (or alternatively prepared by the Competent Authority), which covers health and environmental effects over the whole lifecycle of the substance (HSE, 1994).

There are around 400 new substances notified in the EU each year, of which around one third are notified in the UK. Data on new substances submitted by industry are reviewed by the competent authorities (currently the HSE and the DETR, assisted by the Environment Agency), which are also responsible for reviewing notifications submitted in other Member States.

Existing Substances

For existing substances, Regulation 793/93 introduced a requirement for producers and importers of substances that were on the market before 1981 to submit data to the authorities on those substances. For chemicals produced or imported in quantities below 1,000 tpa but above 10 tpa, these data relate only to a general identification of the substance, details of its expected use pattern and any classification and labelling requirements that apply. For substances produced or imported at over 1,000 tpa, companies are also required to supply data on physicochemical properties; on pathways and environmental fate; on the ecotoxicity and acute and subacute toxicity of the substance; and on carcinogenicity, mutagenicity and/or reproductive toxicity. However, this requirement relates to the provision of existing data and does not require the carrying out of new tests upon animals.

Additionally, there is a requirement to conduct risk assessments for human health and the environment for those existing substances that are placed upon lists of 'priority substances'. Of 110 substances on the first three priority lists (the fourth was only published in October 2000), the first draft risk assessments have been completed for 81. The UK has been responsible for 19 assessments plus the environment aspects of a further two. All UK assessments have been tabled for EU discussion at some level and some assessments have now been finalised and published.

In addition to the regulatory requirements, the International Council of Chemical Associations (ICCA) has undertaken to complete hazard assessments for 1,000 HPV chemicals by 2004. Data are to be produced according to the OECD's Screening Information Data Set (SIDS) Programme. Companies that produce these chemicals are responsible for collection and/or generation of the data, with primary responsibility allocated to 'lead company' and co-sponsor companies contributing to costs according to production volume or another mutually agreed system.

⁴ 'New Substances' are those which are not included on the 1981 European Inventory of Existing Commercial Chemical Substances (EINECS).

It has been assumed here that data from UK companies resulting from the ICCA initiative will be reviewed by the Competent Authorities in the UK. It has also been assumed that this programme will continue beyond 2004, with data on all HPV substances completed by 2020.

It is further assumed that risk assessments under the Existing Substances Regulation will continue, with additional priority substances being allocated to the Member States for risk assessment and recommendation of risk reduction strategies. Competent Authorities will also remain responsible for review of non-UK risk assessments and risk reduction strategies.

3.2.2 The UK Chemicals Strategy

The focus of the UK Chemicals Strategy is on reducing the environmental impacts of chemicals rather than occupational health effects. It can, however, also be expected to result in some health benefits to both the general public and workers. The Strategy is complemented though by the HSE's stated aim to reduce the incidence of work-related ill-health, including that associated with chemicals, by 20% by 2010.

New Substances

The UK Government published its Chemicals Strategy in December 1999 (DETR, 1999). For the purposes of this RIA, it has been assumed that, for new substances, the system of notification - and the associated data requirements - would be unchanged from those set out above for the Base Legislation scenario. The key changes relate to existing substances.

Existing Substances

This scenario builds on the requirements for existing substances under the Base Legislation scenario. Additional requirements under this scenario include those arising from the Stakeholder Forum. One such requirement is for industry to collect data on substances of concern as identified by the Forum. We have assumed that the Forum identifies some 50 chemicals of concern with the period covered by this analysis. There would also be a requirement to make available sufficient data to characterise the hazards of all commercially produced substances by 2020 (with this assumed to relate to some 20,000 substances for which such data will not otherwise exist).

Under this option, data preparation under the ICCA initiative is assumed to take place within an accelerated timeframe (by 2015, as compared to 2020 for the Base Legislation scenario) after the initial 1,000 chemicals have been assessed in the period running up to 2004. It is assumed that the UK regulators would be responsible for reviewing the data prepared by UK industry.

It also is assumed that assessments under the Existing Substances Regulation would continue, with a total of 400 more substances being assessed by EU authorities over the 20year period. In terms of control of the risks associated with downstream uses, it is assumed (as suggested by the Strategy) that the COSHH assessment system would be

extended to cover environmental as well as human health risks (although no costs for so doing have been included in the analysis). Preparation of risk reduction strategies by the UK Government would also continue under the Existing Substances Regulation, with additional risk management measures (where required) resulting from the work of the Stakeholder Forum.

3.2.3 The EU White Paper

New Substances

It is assumed that 50% of notifications in the UK relate to chemicals marketed in less than one tonne. This is an approximate figure since the actual number will vary from year to year. Under the White Paper, there would be no requirement for registration of these substances due to the raised threshold (although industry would be required to “generate the necessary safety data and keep the records available” for substances marketed below the thresholds).

Existing Substances

As suggested in the White Paper, it is assumed here that around 30,000 existing substances will be subject to the registration procedure. Consultation for this partial RIA has not indicated any reason to contradict this figure. The relevant quantities in which these substances are assumed to be produced (hence triggering the need for submission of certain information under the REACH system) are outlined in Table 3.2. In the estimation of costs, UK industry and regulators are estimated to be responsible for 12% of the work undertaken, based on the UK’s share of EU chemical production.

The key testing requirements introduced at the registration stage are assumed to be as follows:

- for existing substances produced or imported at 1 to 10 tpa⁵ available data should be submitted but extra testing should generally be limited to in vitro methods;
- for those produced or imported at 10 to 100 tpa and at 100 to 1000 tpa, there would be a requirement to submit Base Set and Level 1 data⁶ respectively; and
- for substances produced or imported at over 1000 tpa, there would be a requirement to submit Level 2 data.

The testing requirements for *existing* substances will generally follow the current system for *new* substances. The dossier of information for registration includes additional requirements, particularly for data on the properties of substances, a preliminary risk assessment of the intended uses and proposed risk management measures.

⁵ Where there is currently no requirement to submit data under Regulation 793/93.

⁶ In contrast, the current requirement under Regulation 793/93 is to submit very basic substance data only.

Preliminary risk assessments will, where necessary, be supplemented by targeted risk assessments. There are also assumed to be requirements for risk assessments to be undertaken by downstream users where the use is different from that originally intended by the manufacturer (and the authorities so require following notification of that use).

The authorities will be responsible for reviewing all of the data submitted by industry, including risk assessments, risk management measures and testing data (although for many of the substances undergoing registration, checking will be limited to spot-checks - assumed here to affect one out of ten substances).

For substances of very high concern⁷, the authorisation procedure will essentially involve the introduction of a 'positive list', with particular uses of chemicals being permitted by the authorities following submission by the producer of an assessment covering the whole life cycle of the substance (this may include consideration of the socio-economic implications).

Data Requirements

The EU White Paper sets out various requirements for industry to produce data on the properties of new and existing substances. These are outlined in Table 3.5. There is also a requirement, as stated above, for industry to submit information on:

- the intended uses of chemicals and their estimated human and environmental exposure (including a preliminary risk assessment);
- the production quantity envisaged;
- proposals for classification and labelling;
- a Safety Data Sheet; and
- proposed risk management measures.

3.2.4 Other Controls on Chemicals

Under each of the scenarios, other controls upon chemicals would remain in place. Many of these controls are triggered by classification of a chemical's hazards (and in some cases its risks). They include⁸:

- UK, Community and international legislation relating to the transport of dangerous substances;
- requirements on producers and suppliers of substances and preparations to provide information to users on hazard information, according to the CHIP Regulations;

⁷ CMR substances, those with POPs characteristics and endocrine disrupters.

⁸ Based mainly upon DETR (1999) and Dti (nd).

Quantity	Current Situation		White Paper ^a
	New Substances	Existing Substances	
Less than 10 kg	None	None	Industry to keep records
10 to 100 kg	'Reduced'		
Less than 1 tonne	'Reduced'		
1 to 10 tonnes	Base set		Limited to in vitro
10 to 100 tonnes	Lower Level 1	Basic information (Annex 4 of 793/93)	Base set
100 to 1000 tonnes	Upper Level 1		Level 1
Over 1000 tonnes	Level 2	Detailed <i>available</i> information (Annex 3 of 793/93)	Level 2

^a There will be exemptions from testing where there is considered to be sufficient justification

- requirements on employers to protect the health of employees and others under the Control of Substances Hazardous to Health (COSHH) Regulations (e.g. through occupational exposure limits), with the level of control dependent upon the classification requirements for those substances and preparations covered by the classification and labelling regime;
- in relation to buildings containing dangerous substances and preparations, various legislation applies, such as planning and building regulations, control of major accident hazards and fire safety regulations. There also exists legislation relating to the storage of chemicals; and
- requirements on the control of pollution under Local Air Pollution Control (LAPC) for Part B processes and Integrated Pollution Control (IPC) for Part A processes⁹, as well as further controls on emissions of emissions to water through discharge consents.

The costs and the level of protection afforded by these controls may be affected by the scenarios outlined above. For example, the number of chemicals falling under different hazard classifications may change, triggering different requirements for transport, information provision and control measures. Within this partial RIA, however, it has not been possible to estimate the extent of these secondary impacts.

⁹ Under ongoing changes to the legislation, the IPC regime will be replaced by one of Integrated Pollution Prevention and Control (IPPC), which will also extend to some processes currently covered by the LAPC regime and some not yet covered.

Table 3.1: Scenario Assumptions for Registration Procedures for New and Existing Substances

	Base Legislation Scenario		UK Chemicals Strategy		EU White Paper Strategy	
	Assumption	Timing		Timing		Timing
New Substances	<ul style="list-style-type: none"> Approximately 400 per annum (10kg and greater go through registration across EU; around one third (130) registered in UK, half of which (65) are by UK companies. One half of substances registered in quantities of <1 tonne (25% of these later marketed in larger quantities) Assume process requires the preparation of Base Set data or equivalent for all substances to be marketed in quantities >10 kg Assume 130 processed in UK per annum 	2001-20	<ul style="list-style-type: none"> Approximately 400 per annum (10kg and greater) go through registration across EU; around one third (130) registered in UK, half of which (65) are by UK companies. One half of substances registered in quantities of <1 tonne (with around 25% of these later marketed in larger quantities) Assume process requires the preparation of Base Set data or equivalent for all substances to be marketed in quantities >10 kg Assume 130 processed in UK per annum 	2001-20	<ul style="list-style-type: none"> Assume that 50% of those currently going through registration are produced in volumes below 1t threshold (as is case in UK); suggests that 200 chemicals will go through proposed EU registration system Average of 32.5 new chemicals > 1 tonne processed in UK 	2001-20
Existing Substances	<ul style="list-style-type: none"> Classification and Labelling requirements Data requirements under ESR for HPVs and LPVs 	2001-20 2001-20	<ul style="list-style-type: none"> As per Base Legislation scenario Data collection for 50 chemicals of concern as identified by Stakeholder Forum Hazard characterisation data required for all commercially produced chemicals; assume data required for 20,000 additional substances 	2001-20 2001-04 2004-15	<ul style="list-style-type: none"> 30,000 substances to be registered: <ul style="list-style-type: none"> - 20,000 at 1 - 10 tonnes - 5,300 at 10 -100 tonnes - 2,500 at 100 -1,000 tonnes - 2,500 at >1,000 tonnes UK will account for 12% of these based on share of EU industry turnover Dossier to be provided including preliminary risk assessment of intended uses and risk management proposals as appropriate 	2001-12 2001-12 2001-08 2001-05

Table 3.2: Scenario Assumptions for Testing Procedures for New and Existing Substances

	Base Legislation Scenario		UK Chemicals Strategy		EU White Paper Strategy	
	Assumption	Timing		Timing		Timing
New Substances	<ul style="list-style-type: none"> No testing requirements assumed in addition to those undertaken as part of preparation of Base Set data and submission (covered by registration) 	2001-20	<ul style="list-style-type: none"> No testing requirements assumed in addition to those undertaken as part of preparation of Base Set data and submission (covered by registration) 	2001-20	<ul style="list-style-type: none"> Increased threshold for submission of data 	2001-20
Existing Substances	<ul style="list-style-type: none"> ICCA programme on HPV chemicals with first 1,000 assessed by 2004; EU responsible for 260 chemicals and UK industry likely to do about 100 of these. Assume by 2020 that Base Set data available for all 4,100 HPVs are produced by industry; EU responsible for 1,500 chemicals, with the UK doing a further 200 (20%) during this second stage 	2001-04 2004-20	<ul style="list-style-type: none"> ICCA programme on HPV chemicals with first 1,000 assessed by 2004; UK industry likely to do 100 of these. Under accelerated programme, assume by 2015 that Base Set data available for all 4,100 HPVs are assessed; UK doing 200 (20%) during second stage 	2001-04 2004-15	<ul style="list-style-type: none"> Different testing requirements apply based on quantity: <ul style="list-style-type: none"> - Testing as part of Base Set data for chemicals produced in quantities 10t - 100t - Level 1 testing for chemicals produced in quantities >100t - Level 2 testing for quantities produced >1000t Testing for unintentional uses of concern as agreed with competent authorities 	2001-12 2001-10 2001-12

Table 3.3: Scenario Assumptions for Evaluation Procedures for New and Existing Substances

	Base Legislation Scenario		UK Chemicals Strategy		EU White Paper Strategy	
	Assumption	Timing		Timing		Timing
New Substances	<ul style="list-style-type: none"> No evaluation procedures assumed other than those performed as part of notification (see separate table) 	2001-20	<ul style="list-style-type: none"> No testing requirements assumed in addition to those undertaken as part of preparation of Base Set data and submission (covered by registration) 	2001-20	New and Existing Substances <ul style="list-style-type: none"> Competent Authorities undertake spot-checks on data submitted by industry. Assumed that 1 out of 10 chemicals are subject to a spot-check, with this applying to 1,300 new substances and 3,000 existing substances within the UK 	2001-12
Existing Substances	<ul style="list-style-type: none"> UK Authorities review results under the ICCA programme produced by UK industry Data for 100 chemicals under first phase Data for 200 chemicals during second phase 	2001-04 2004-20	<ul style="list-style-type: none"> UK Authorities review results under the ICCA programme produced by UK industry Data for 100 chemicals under first phase Data for 200 chemicals during second phase 	2001-04 2004-20		

Table 3.4: Scenario Assumptions for Notification and Authorisation Procedures for New and Existing Substances

	Base Legislation Scenario		UK Chemicals Strategy		EU White Paper Strategy	
	Assumption	Timing		Timing		Timing
New Substances	<ul style="list-style-type: none"> Notification of new substances as under current legislation, with 130 per annum going through process in the UK Additional costs for Competent Authorities of reviewing non-UK notifications 	2001-20	<ul style="list-style-type: none"> Notification of new substances as under current legislation, with 130 per annum going through process in the UK; Competent Authority costs recharged Additional costs for Competent Authorities of reviewing non-UK notifications 	2001-20	New and Existing Substances <ul style="list-style-type: none"> Expected some 1400 substances to go through authorisation procedures (CMRs, POPs, endocrine disrupters, PBTs, etc). Targeted testing and risk assessments prepared for specific chemicals of concern; assume that about 30% are produced in quantities of <100 tonnes, suggesting that some 500 will require additional testing and risk assessment Industry preparation of RRS for above chemicals with review of these by Competent Authorities Risk assessments and risk reduction strategies for unintentional uses of concern Review of risk assessments and RRS prepared by downstream users 	2010-12 for >1000t and 2012-15 for >100t

Table 3.4: Scenario Assumptions for Notification and Authorisation Procedures for New and Existing Substances

	Base Legislation Scenario		UK Chemicals Strategy		EU White Paper Strategy	
	Assumption	Timing		Timing		Timing
Existing Substances	<ul style="list-style-type: none"> ESR risk assessments of priority substances continues with 400 chemicals completed by 2020; UK responsible for 80 of these chemicals Preparation of risk reduction strategies by UK Authorities, assuming 80% of those going through RA require a strategy Competent Authority review of non-UK risk assessments and risk reduction strategies 	<p>2001-20</p> <p>2001-20</p> <p>2001-20</p>	<ul style="list-style-type: none"> ESR risk assessments of priority substances continues with 400 chemicals completed by 2020; UK responsible for 80 further chemicals Preparation of risk reduction strategies by UK Authorities, assuming 80% of those going through RA require a strategy Competent Authority review of non-UK risk assessments and risk reduction strategies Industry risk assessments for first set of chemicals of concern (as identified by Stakeholder Forum); assume 50 chemicals requiring further testing, risk assessment and risk management, with review by Stakeholder Forum reviews risk assessments Industry preparation of risk management proposals (42 chemical) for submission to Stakeholder Forum Authorisation of voluntary industry proposals and enforcement where industry fails to meet Strategy targets 	<p>2001-20</p> <p>2001-20</p> <p>2001-20</p> <p>2001-05</p> <p>2005-10</p> <p>2005-20</p>		

4. BENEFITS

4.1 Types of Benefits

The main types of potential benefit associated with the proposals set out in the EU White Paper, compared to the other scenarios, are:

- registration and evaluation of additional information on the risks associated with chemicals, enabling risk management measures to be introduced more rapidly and thus avoiding damage to health and the environment caused by chemicals. The information will also be made available to consumers, enabling them to make product choices on the basis of information on chemical risks. These benefits will accrue to users of chemicals and to society as a whole;
- authorisation of the use of substances giving rise to very high concern except where risks can be demonstrated as acceptable, thus avoiding potential damage to health and the environment associated with such substances. These benefits will also accrue to users of chemicals and to society as a whole; and
- reduction in the costs of bringing new chemicals to market. These benefits will accrue to manufacturers and, if they result in reduced prices and/or improved chemicals coming to market sooner, to users of chemicals.

There are also potential benefits to certain stakeholders through the transfer of responsibilities and related costs from the Competent Authorities to industry, and from manufacturers to users of chemicals within industry. However, these may be offset by changes in the overall costs associated with the strategy.

4.2 Provision of Additional Information on Chemical Risks

4.2.1 Introduction

The three options vary in terms of:

- the numbers of chemicals on which risk information will be provided;
- the nature of the information to be provided; and
- the timescale over which the information will be provided.

These variations are summarised in Table 4.1, based on the scenario assumptions described in Section 3 and summarised in Tables 3.1 to 3.4. Benefits to the UK are assumed to arise in relation to all chemicals for which additional information is provided, not just those that are the responsibility of UK industry and authorities.

4.2.2 Registration and Evaluation of New Substances

The Base Legislation and UK Chemicals Strategy scenarios are similar in their treatment of new chemicals. Both require notification of all new chemicals placed on the market in quantities over 10kg. For chemicals marketed in quantities below one tonne, this consists of a 'reduced data set', together with an assessment of the risks posed by use of the substance. For chemicals placed on the market in larger quantities, this information is supplemented by additional data, with the amount of testing required dependent upon the quantity of chemical.

Under the proposed EU White Paper scenario, no registration will be required for substances placed on the market in quantities below one tonne. For substances placed on the market in quantities between one and ten tonnes, no animal testing will be required. In the UK, it is estimated that around half of the new substance notifications received to date have been for substances placed on the market in volumes less than one tonne. Approximately 25% of these are later marketed in larger quantities, which would trigger registration requirements under the proposed EU strategy.

The Base Legislation and the UK Chemicals Strategy thus have benefits compared with the EU White Paper scenario in providing information on the risks associated with chemicals placed on the market in quantities below one tonne. It is not known what level of risks might be associated with chemicals placed on the market in these quantities, although the White Paper notes that 70% of new substances notified are found to be potentially hazardous. However, the level of exposure will normally be lower than for chemicals marketed in higher quantities and should a chemical be marketed later in higher quantities then registration will be required. The Base Legislation and UK Chemicals Strategy also have the benefit of providing additional information on chemicals placed on the market in quantities between one and ten tonnes. Again, the risks associated with such chemicals, and thus the extent of this benefit, are not known.

4.2.3 Registration and Evaluation of Existing Substances

The main difference between the three options lies in the provision of data on the hazards associated with existing substances.

Under the Base Legislation scenario and UK Chemicals Strategy, it is assumed that information will be provided under the ICCA programme on all 2,500 HPV substances on the European market by 2020, with information on the first 1,000 by 2004. This information will comprise the OECD SIDS set plus a hazard assessment. Under the EU strategy, registration data (including an initial risk assessment and development of risk management measures) will be provided on all 2,500 substances by 2005, with Levels 1 and 2 testing completed, where appropriate, by 2010. The EU proposals thus have the benefit of providing more detailed information, more quickly, than the other options on the substances where exposure levels are highest.

For substances on the market in lower quantities, the Base Legislation scenario provides only limited information, in the form of dossiers submitted under requirements on classification, packaging and labelling of dangerous substances. A review by the

European Chemicals Bureau (ECB, 1999) indicated that, even for HPV substances, only 21% of dossiers had data equivalent to Base Set requirements under the Existing Substances Regulation. The proportion is likely to be even lower for non-HPV substances; however, risk management measures for these chemicals are provided through safety data sheets.

Under the UK Chemicals Strategy, 'hazard characterisation' information would be provided on 20,000 non-HPV 'commercially available' chemicals by 2020. The precise form of this information is not yet clear. The EU White Paper scenario requires registration data on around 27,500 non-HPV chemicals, including initial risk assessments and potential risk management measures, to be submitted by 2008 or 2012, depending on quantities. Appropriate test data is to be submitted by 2012. In estimating the costs associated with this requirement, we have assumed that data will already be available on 5,000 of these substances. Such information, however, is not yet in the public domain and therefore benefits will accrue from the availability of information on the roughly 27,500 chemicals. The EU scenario thus again has the benefit of providing additional information, more quickly, on the risks associated with existing chemicals than the other scenarios. The UK Chemicals Strategy similarly has benefits compared with the Base Legislation scenario.

The Base Legislation scenario and the UK Chemicals Strategy have no requirements concerning information on downstream uses of chemicals. The EU White Paper requires users to inform the authorities of any uses of chemicals not envisaged by the manufacturers of the chemical. The authorities may then require the preparation of Base Set and testing data, together with additional data on exposure and an initial risk assessment and any risk management measures. The EU scenario therefore has the benefit, compared with the other strategies, of providing information on risks associated with the downstream use of chemicals.

4.3 Restrictions on Substances of Concern

All three scenarios enable restrictions to be placed on the use of substances considered to pose particularly significant risks. For the Base Legislation scenario this takes the form of the Existing Substances Regulation requirements for full risk assessment and the development of recommendations on risk management, which may include restrictions on marketing and use, for substances designated as posing high risks. Currently, 140 such substances have been designated; the Base Legislation scenario assumes that a further 260 substances will be designated and assessment of these will be complete by 2020, despite the slow progress to date.

These requirements will also remain in place under the UK Chemicals Strategy. In addition, chemicals identified by the Stakeholder Forum as being of particular concern will be subject to testing, risk assessment and the development of risk management measures that may include restrictions on their use. This is anticipated to cover a further 50 substances by 2004, with an unknown number of others to be identified by the Stakeholder Forum between 2005 and 2020.

The EU White Paper places a prohibition on the use of substances of very high concern, of which there are estimated to be 1,400. Use of the substances will only be permitted following full testing, risk assessment and development of risk management measures that will result in a negligible risk.

The EU White Paper thus has the benefit, compared with the other options, of restricting the use of a larger number of high-concern chemicals, more quickly. The UK Chemicals Strategy has benefits compared with the Base Legislation scenario of increasing the number of chemicals of concern that may be subject to restrictions on use, and of involving stakeholders in identifying the chemicals of most concern.

4.4 Potential Value and Timing of the Benefits

4.4.1 Value of the Benefits

The value of the benefits arising from the additional and earlier information on chemical risks will depend upon the extent to which it results in risk management measures that deliver real reductions in the incidence of damage to health and the environment. This is impossible to predict at this stage. Nevertheless, an indication of the potential benefits can be obtained by looking at the costs of current health and environmental damages associated with chemicals. It must be noted though that such costs represent an estimate of the maximum benefits that could be obtained.

Information is available from the HSE on the current level of occupational injuries and ill health in the UK associated with chemicals and the estimated costs of these. No comparable information, however, is available on the current level of environmental damage associated with chemicals. Where significant risks to the environment from chemicals have been identified, they are currently subject to control under existing regulations (see 3.2.4). Information is also lacking on the health effects occurring within the general public as a result of environmental exposures (as opposed to occupational exposure).

The HSE noted in its Regulatory Impact Assessment of the CHIP 99(2) Regulations that exposure to or contact with harmful substances is responsible for 5-10 fatal incidents, around 1,000 major injuries and around 4,000 further incidents resulting in at least three days absence from work each year. This is potentially an under-estimate, as not all incidents involving harmful substances are, in practice, reported to the HSE. The HSE identified the potential benefits associated with prevention of chemicals-related fatalities and injuries at a present value of between £64 million and £129 million over 10 years (based on willingness to pay values to reduce the risk of death or injury).

The CHIP 99(2) RIA also identifies the costs arising from ill health associated with chemicals, including asthma, dermatitis and cancer together with other effects. The total costs to society of occupational asthma are estimated at £37,000 per new case, the majority of which is lost income to the individual (and therefore lost output to society as a whole). There are estimated to be between 1,500 and 3,000 new cases of chemical-related occupational asthma per year, giving an estimated total net present value cost over

10 years of between £500 million to £1 billion. The HSE estimates that the known cost of occupational dermatitis cases is around £2,000 each, excluding an unknown level of lost income. Around 4,000 cases of chemical-related occupational dermatitis are reported each year, which may be around half the total number arising. The net present value cost of dermatitis over 10 years is estimated by the HSE at £80-160 million. It should be noted that these costs are the direct costs of illness only, and do not include an element of individuals' willingness to pay to avoid illness.

No comparable data are available on the costs associated with cancer from occupational exposure. Around 3,000 to 12,000 work-related cases of cancer arise each year. Of these, around 1,300 cases of malignant mesothelioma and 1,500 cases of lung cancer are associated with asbestos, indicating a maximum number of chemical-related cases of cancer ranging from around 200 to 9,000.

From the above, a total estimate can be made of the maximum potential benefits that could arise from the provision of additional information on health from chemicals, with this assuming that subsequent risk management activities reduces all cases of chemicals related ill-health:

- reduced costs of occupational injuries and fatalities amounting to £64-129 million over 10 years;
- reduced costs of occupational asthma and dermatitis totalling £580 million to £1.2 billion over 10 years; and
- unknown benefits arising from reduced costs associated with cancer from occupational exposure, non-occupational exposure and environmental damage associated with chemicals.

Three points should be noted concerning the above figures. Firstly, and as noted above, the estimates combine a mix of economic data, some reflecting individuals' willingness to pay to avoid a risk while others reflect only medical and related costs of illness. As a result, the figures are unlikely to capture the full economic costs associated with chemical related ill-health. Furthermore, the willingness to pay values quoted above for reducing chemicals related fatalities and ill-health are 'transfer' values (based on other forms of accidental death and injury) and are not specific to chemicals. They therefore may represent either an over-or under-estimate of true willingness to pay to avoid such impacts from chemicals.

Of greater importance is that in practice it is unlikely that any of the scenarios would lead to a reduction of all chemical-related ill-health and injury, so that the actual benefits would be lower (and potentially by a significant amount) than these maximum values. The benefits are, however, recurring and would continue beyond the period covered by this assessment. Some benefits will arise under each of the options, and it has not proved possible to estimate the relative benefits that each option would provide. However, in considering the potential likely increase in benefits delivered by the EU White Paper scenario over the UK Chemicals Strategy scenario, it should be remembered that under

the latter the HSE has set a target to reduce worker-related ill-health associated with chemicals by 20% by 2010.

Finally, for these benefits to occur, the provision of additional data must be followed by the introduction of effective risk management measures. Whatever form these may take, costs will arise from their introduction.

4.4.2 Timing

The timing of benefits under each of the scenarios will depend upon how quickly risk reduction takes place. In the case of the Base Legislation scenario and the UK Chemicals Strategy, and for substances not subject to authorisation under the EU White Paper proposals, this will probably take at least five years from initial identification of potential risk management measures.

This means that the full benefits for existing HPV chemicals will not arise until 2015 under the EU White Paper Strategy, 2020 under the UK Chemicals Strategy and 2025 under the Base Legislation scenario. Some proportion of the benefits would occur earlier than these end dates though. The full benefits associated with substances on the market in smaller quantities will arise later still. The benefits will, of course, continue beyond the above dates.

For substances subject to authorisation under the EU White Paper scenario, the benefits will arise immediately the strategy enters into force, as the use of such substances will be prohibited until measures posing negligible risks can be put into place. Under the UK Chemicals Strategy, the benefits of risk management measures for the first 50 chemicals of concern may arise between 2005 and 2010; for other chemicals of concern the benefits will be realised later. Benefits under the Existing Substances Regime will arise over the period from 2004, as risk assessments and accompanying risk reduction strategies are completed.

4.5 Reduced Costs of Bringing New Substances to Market

Compared to the Base Legislation scenario and the UK Chemicals Strategy, the EU White Paper proposals would reduce the costs of bringing new substances to market by:

- removing the requirement for registration of new substances placed on the market in quantities below one tonne (and increasing the period of exemption from one to three years); and
- reducing the level of testing required for substances placed on the market in quantities between one and ten tonnes.

According to industry, most (though not all) new substances will initially be placed on the market in quantities below one tonne. This is confirmed by HSE data showing that around 50% of notifications under NONS are for quantities below one tonne, accounting for around 65 notifications per year (out of 130). Assuming that the cost of notification

of such substances is £85,000 per chemical¹⁰, this gives net present value savings of around £34 million. These savings would, of course, be recurring and would continue beyond the period covered by this analysis. Around 25% of chemicals initially notified in quantities below one tonne are later produced in higher quantities. For these substances, therefore, the costs would be delayed rather than avoided.

This estimate assumes that the number of new substances brought to market by UK firms will remain similar to current levels. In practice, this may not be the case; discussions with industry indicate that, under the proposals set out in the EU White Paper, the number of new substances notified might increase. It has not been possible, however, to identify what the level of increase might be or over what time-period it might be realised.

Reducing the level of testing required for substances between one and ten tonnes will also result in reduced costs. Currently, such substances require full Base Set data. Under the EU strategy, they will require only *in vitro* testing, reducing the cost per substance. Unfortunately, it is not clear what proportion of the 65 new chemicals notified in the UK each year fall within this size range. It seems likely, though, that the majority of chemicals in this size range will later be marketed in larger quantities, so that the costs are deferred rather than avoided.

Although the cost savings are not large they are, according to industry, significant in relation to the risks that a chemical may not prove to be commercially viable. As well as savings in costs for the numbers of new substances currently notified, the exemption for substances below one tonne may also encourage manufacturers to bring additional new substances to market. Industry notes that, since the introduction of notification requirements for new substances, 90% fewer new substances have been brought to the market in Europe than in the USA. As well as providing benefits to manufacturers, bringing additional new substances to the market can generate benefits for users in terms of cost and efficiency. There may be additional benefits, as combining the reduction of costs in bringing new chemicals to market with increased controls over existing chemicals could encourage a switch to lower risk chemicals.

The reduction in the costs of bringing new substances to market will have particular benefits for SMEs. Consultation with chemical industry trade associations indicates that SMEs can be significant innovators, particularly in specialty chemical development. Generally, the market for new specialty chemicals will be smaller than for new bulk chemicals, so that the costs of initial registration of substances represents a proportionately higher burden. They are also likely to be produced in smaller quantities for a longer period than bulk chemicals, so that the reduced testing requirements for quantities below 10 tonnes may also bring particular benefits.

¹⁰ The costs quoted in the EU White Paper for preparation of Base Set data.

Table 4.1: Data Availability and Timing under Scenario Assumptions for Registration Procedures for New and Existing Substances

	Base Legislation Scenario			UK Chemicals Strategy			EU White Paper Strategy		
	Data	Number	Timing	Data	Number	Timing	Data	Number	Timing
New Substances	10kg-1t: basic data 1-100t: Base Set, risk assessment 100-1000t: Base Set, Level 1, risk assessment >1000t: Base Set, Level 1+2, risk assessment	4,000 (1,300 in UK) } } }4,000 (1,300 in UK) } }	2001-2020 2001-2020	10kg-1t: basic data 1-100t: Base Set, risk assessment 100-1000t: Base Set, Level 1, risk assessment >1000t: Base Set, Level 1+2, risk assessment	4,000 (1,300 in UK) } } }4,000 (1,300 in UK) }	2001-2020 2001-2020	10kg-1t: no data 1-10: basic data, initial risk assessment + RMM 10-100t: Base Set, initial risk assessment + RMM 100-1000t: Base Set, Level 1, initial risk assessment + RMM >1000t: Base Set, Level 1+2, initial risk assessment + RMM	4,000 } } } }4,000 (1,300 in UK) } }	2001-2020
Existing Substances	ICCA HPV programme: SIDS, hazard assessment Classification, Packaging and Labelling data (only 21% have SIDS or above) Existing Substances Regulation: full risk assessment + RMM	1,000 2,600 4,800 400	2004 2020 complete 2020	ICCA HPV programme: SIDS, hazard assessment All commercially produced chemicals: hazard characterisation Existing Substances Regulation: full risk assessment + RMM Chemicals of concern: testing, risk assessment +RMM	1,000 2,600 20,000 400 50	2004 2015 2020 2020 2004	>1000t: Base Set, Level 1+2, initial risk assessment + RMM 100-1000t: Base Set, Level 1, initial risk assessment + RMM 10-100t: Base Set, initial risk assessment + RMM 1-10: basic data, initial risk assessment + RMM Substances of very high concern: Base Set, Level 1+2, risk assessment + RMM Downstream uses: Base Set, other testing, risk assessment and RMM	2,500 2,500 5,300 20,000 1,400 3,000	2005/ 2010 2008/ 2012 2012 2012 2012

5. COSTS

5.1 Introduction

The additional requirements imposed by the strategy set out in the EU White Paper may affect a large number of sectors and organisations within the UK. Direct costs will arise to the UK chemicals industry, where this includes manufacturers of the range of industrial and specialty chemicals. In addition, formulators, those using chemical intermediates and others reliant upon chemical inputs to their processes may be affected by the requirements placed on downstream users. Government bodies, in their role as Competent Authorities, will also be directly impacted through both the creation of new duties and the transfer of some current activities to industry.

The majority of the direct costs imposed by the White Paper, compared to the other options, relate to existing chemicals. They are therefore ‘one-off’ costs in that, once all existing chemicals on the market have met the requirements of the strategy, additional costs will not be incurred on a regular basis. By contrast, costs (and savings) associated with new chemicals will be incurred whenever such chemicals are placed on the market. For the purposes of this analysis, the total costs incurred over a 20-year period have been assessed.

More difficult to determine are the likely indirect and secondary effects which the changes in direct costs will have on UK businesses and consumers more generally. Although beyond the scope of this partial RIA, significant increases in the costs of faced by a range of industry sectors could lead to wider macroeconomic impacts, affecting economic growth and employment more generally.

The aim of the cost analysis presented in this section is to highlight those aspects of the strategy set out in the EU White Paper that are likely to result in the greatest single cost increases and to identify those aspects which represent significant shifts in who bears the costs. The analysis is based on the key assumptions concerning the activities required under each of the three future scenarios as presented in Section 3 (see Tables 3.1 to 3.4). The assumptions are further developed here to allow preliminary estimates to be made of the costs arising to UK organisations under each scenario.

It must be recognised that many of the assumptions, and hence associated costs, are highly uncertain. This is particularly true for elements of the EU White Paper scenario, but also applies to aspects of the UK Chemicals Strategy. In order to provide some insight as to the implications of these uncertainties, an extensive sensitivity analysis is presented in Annex 3 to this report.

5.2 Key Assumptions and Associated Costs

The data used to derive the cost estimates comes from a number of sources, as follows:

- consultations with the CIA and various industry representatives, including those from the chemicals industry and from downstream user sectors;
- consultations with HSE, PSD, DTI and SEPA; the HSE in particular provided detailed cost data for the different regulatory activities of concern; and
- figures quoted in the report on testing requirements under the EU White Paper scenario (IEH, 2001), in the *UK Chemicals Strategy* (DETR, 1999) and in the EU White Paper (EC, 2001).

In addition, the consultants have drawn on their own experience to provide estimates for certain of the cost items (e.g. for the types of work that the UK government has put out to contract in the past).

Table 5.1 presented at the end of this section summarises the assumptions that have formed the basis for the cost analysis. Particular attention should be paid to the data set out in the table when considering the estimated costs.

For each of the procedural stages defined for this RIA, the table sets out the activities giving rise to costs, the number of chemicals assumed to be affected and the costs per chemical affected. It will be noted that figures are given for the number of chemicals assumed here to be affected by a particular activity at the EU level and then the share of these which would fall to UK industry or UK regulators. In general, where commitments are EU-wide, we have assumed that the UK takes responsibility for 20% of chemicals for the Base Legislation and UK Chemicals Strategy (in line with current commitments under the ICCA programme), or takes responsibility for 12% under the EU White Paper scenario (in line with the proportion of the EU chemical industry's output accounted for by UK industry). Sensitivity testing of these assumptions are presented in Annex 3.

Cost figures for Base Set data preparation and Levels 1 and 2 testing are available from three different sources, with there being significant differences between the sources. The resulting range is given in Table 5.1 (with further details provided in Annex 3). In addition, in some cases, the figures given in the table represent the combined or average costs for meeting different data and testing requirements. All important assumptions are spelled out in the table (and discussed further in Annex 3).

5.3 Total Costs under Each Scenario

5.3.1 Introduction

Based upon the data provided in Table 5.1, present value (PV) cost figures have been developed for each of the three scenarios. These are presented in Table 5.2, using cost data provided by UK industry (which is focused on use of UK testing facilities) and assuming a 6% discount rate over the period of 2001 to 2020 (see Annex 3 for the changes in costs arising under different cost assumptions and an 8% discount rate).

Table 5.2: Present Value Costs Estimates (industry data, 6% discount rate over 20 years)

<i>Base Legislation Scenario</i>		
Stage	Cost Item	PV Costs
Registration	Base Set data plus risk assessment	68,896
Testing	ICCA stage1	7,805
	ICCA stage2	9,347
Evaluation	CA review	1,496
Notification and Authorisation	Notification <1t	1,621
	Notification >1t	6,890
	HSE Risk assessment	2,594
	EA Risk assessment	3,741
	CA review of non-UK ESR Ras	1,590
	CA RRS	2,026
	CA review of non-UK ESR RRS	1,135
Total Present Value Costs		107,141
<i>UK Chemicals Strategy Scenario</i>		
Stage	Cost Item	PV Costs
Registration	Base Set data plus risk assessment	68,896
	Stakeholder Chemicals	22,956
	Hazard Data	62,350
Testing	ICCA Stage1	7,805
	ICCA Stage2	10,505
Evaluation	CA review	1,496
Authorisation	Notification <1t	1,621
	Notification >1t	6,890
	HSE Risk assessment	2,594
	EA Risk assessment	3,741
	CA review of non-UK ESR Ras	1,590
	CA RRS	2,026
	CA review of non-UK ESR RRS	1,135
	Industry Ras for Stakeholder	2,233
	Industry RRS for Stakeholder	1,467
Total Present Value Costs		197,305
<i>White Paper Strategy Scenario</i>		
Stage	Cost Item	PV Costs
Registration	SIDS	34,448
	Dossier	52,251
Testing	10-100	66,726
	100-1000	93,799
	>1000	280,409
	Downstream	22,217
Evaluation	CA evaluation	2,494
Notification and Authorisation	Spot Checks	689
	RAS unintentional	22,217
	Additional Testing 500	31,584
	Risk Assessments	4,422
	Risk Reduction	4,422
	CA reviews of RA/RRS	1,061
	CA reviews of downstream	3,777
Total Present Value Costs		620,515

5.3.2 Registration Activities

All three scenarios assume that the number of new substances coming to market through notification in the UK remains at a similar level to that currently occurring (i.e. 130 in total, with half of these greater than 1 tonne). This is reflected in the estimates of the costs faced by industry in preparing pre-registration data for new chemicals as provided in Table 5.2 under the cost item “Base Set” for registration. It should be noted that these PV cost estimates assume that 50% of notifications processed by UK authorities are submitted by non-UK companies (based on HSE data, taking maximum figures). For both the Base Legislation scenario and the UK Chemicals Strategy, these costs represent a significant proportion of total costs, at almost £69 million or 64% and 35% of total costs respectively. This compares to the reduction in costs arising under the EU White Paper requirements, with costs to UK industry associated with new chemicals data preparation falling to about £34 million (about 5% of the total costs of the EU scenario).

As noted in Section 4, discussions with industry indicate that, under the White Paper Strategy, the number of new chemicals brought to market might increase. It has not proved possible, however, to estimate what scale of increase might occur or over what time-period.

Under the UK Chemicals Strategy, it has been assumed here that the requirements placed on industry to gather data on “priority chemicals” form a type of registration requirement for existing substances. The relatively high cost figures indicated in Table 5.2 reflect the fact that it is assumed the Stakeholder Forum identifies some 50 priority chemicals, with each of these requiring further Base Set data collection and testing at an average cost of £500,000. The figure of 50 priority chemicals is likely to be high, given that this work would be in addition to that undertaken as part of the ICCA programme and the Existing Substances Regulation (see Annex 3 for sensitivity testing of this assumption).

Also of note for the UK Chemicals Strategy are the costs for producing hazard data for all commercially produced chemicals. It is unclear from the Strategy what is intended here. For the purposes of this analysis, we have assumed that UK industry must meet the costs of providing hazard characterisation data for some 20,000 chemicals at a cost of £5,000 per chemical. This assumption alone accounts for some £62 million in costs, or roughly 31% of total scenario costs (again, see Annex 3 for sensitivity testing of this assumption).

In comparison, the costs of preparing dossiers in line with the data requirements set out in the EU White Paper are estimated at around £52 million for UK industry. However, owing to significant costs arising under the other requirements of this scenario, these account for roughly 7% of estimated total costs. In total, registration activities account for about 13% of total costs.

5.3.3 Testing

For both the Base Legislation and UK Chemicals Strategy scenarios, testing activities are assumed to relate to those being undertaken by industry in response to the ICCA programme. The costs to UK industry associated with data collection and testing for an

estimated 300 chemicals (over the 20 year time horizon) are estimated at about £17 million and £18 million respectively for the two scenarios. The increased costs under the UK Chemicals Strategy stem from the acceleration in the date by which this data will be available. These costs accounts for around 16% of total costs for the Base Legislation scenario and 9% for the UK Chemicals Strategy.

As would be expected, the situation is very different under the EU White Paper scenario. In this case, the total present value costs of testing are estimated at £463 million for UK industry, where this includes some £22 million for testing to be undertaken by downstream users for non-envisaged uses (i.e. not accounted for in the risk assessment prepared by the manufacturer) posing potential environmental or health risks. These testing requirements account for almost 75% of total strategy costs, and represent the main difference between this scenario and the other two scenarios.

5.3.4 Evaluation

Evaluation relates here to the need for Competent Authorities (CAs, where these are the currently the HSE, and DETR - assisted by the EA) to review the data produced by industry. Under the Base Legislation and UK Chemicals Strategy scenarios this relates to review of the data produced by industry under the ICCA programme, with the costs being fairly small at around £1.5 million. Under the EU White Paper, a proportion of the evaluation work would be carried out by a 'central entity'. As the role and costs of such an entity are not yet clear, we have assumed for the purposes of the assessment that the costs will be incurred by the existing CAs. The costs incurred by the CAs in relation to the White Paper Strategy are greater than for the other options, at around £2.5 million. In this case, the costs relate to the need to undertake spot checks of dossiers submitted for both new and existing substances, with these then leading to decisions concerning the need for further testing and targeted risk assessment as part of notification and authorisation activities.

For none of the scenarios, do these costs account for a significant proportion of total costs.

5.3.5 Notification and Authorisation

As defined here, notification and authorisation cover a range of activities. For the Base Legislation and UK Chemicals Strategy scenarios, this includes the reviews carried out by the CAs on the data submitted for notification of new substances. It also includes the range of risk assessment and risk reduction activities currently occurring under the Existing Substances Regulation and to take place under the auspices of the Stakeholder Forum. For the EU White Paper scenario, this stage relates to the additional testing and targeted risk assessment and risk management activities to be undertaken for the expected 1,400 chemicals of concern and, for the purposes of this RIA, the risk assessments to be produced by downstream users for any non-envisaged uses of concern.

For the Base Legislation Scenario, the estimated total present value costs of these activities is around £19.6 million, with £11 million of this borne by the Competent

Authorities and the remainder by industry (through notification fees). These costs account for just about 18% of the total costs of the scenario.

The costs for notification and authorisation activities are slightly higher under the UK Chemicals Strategy scenario, at an estimated £23 million. The additional costs over the Base Legislation Scenario relate to the increased level of risk assessment activity required by industry under this scenario (where these are assumed to be in addition to the risk assessments and risk reduction strategies prepared by the CAs under the Existing Substances Regulation). These costs account for around 12% of the total present value scenario costs.

In contrast, the additional testing and risk assessment requirements arising under the EU White Paper lead to the costs of authorisation and notification rising to around £68 million, or 11% of total costs. In contrast to the two other scenarios, industry bears all but about £4.7 million of these costs.

5.3.6 Incremental Costs

As a final comparison, it is useful to examine the change in costs implied by moving to the UK Chemicals Strategy and the EU White Paper from the Base Legislation scenario. The total present value costs estimated for each of the scenarios (as presented in Table 5.2) are:

- Base Legislation: £ 107 million;
- UK Chemicals Strategy: £ 197 million;
- EU White Paper: £ 620 million.

From the above figures, it can be seen that the estimated costs of the UK Chemicals Strategy are about £90 million over those of the Base Legislation scenario. In comparison, the EU White Paper results in additional costs of around £513 million over the Base Legislation scenario and £423 million over the UK Chemicals Strategy. These are costs to the UK alone.

It should be noted that these estimates depend upon a range of assumptions about how each of the scenarios will operate in practice and are therefore subject to some uncertainty. Sensitivity analysis suggests that changes in assumptions concerning the costs of testing could add as much as £100 million to the estimates for the EU White Paper, as could assumptions raising the share of chemicals falling to UK industry from 12% to 20% (see Annex 3 for a fuller discussion).

If one carries out a rather simplistic comparison of the above figures to the maximum worker-related health benefits outlined in Section 4, one can see that the additional costs associated with UK Chemicals Strategy scenario may be justified by if it results in the reduction of around 22% of the cases of occupational asthma and dermatitis. It must be remembered though, that the above figures do not include any costs associated with actual risk reduction. Thus, the increased costs arising under the UK Chemicals Strategy are justified by a 15% reduction in occupational asthma and dermatitis if risk reduction

is costless - an unlikely outcome. Whether a balance will be achieved between costs and benefits will depend not only on the costs or risk reduction but also on the additional benefits that would arise from reductions in health effects across the general public together with environmental benefits and greater public confidence.

The case may be more marginal for the EU White Paper, however, with a 70% reduction in the cases of occupational asthma and dermatitis - a highly optimistic assumption - being required to offset the estimated scenario costs alone. Thus, significant further reductions in health effects to the general public, together with environmental benefits and greater public confidence would need to be achieved in order to off-set the additional costs of implementing this strategy and the associated risk reduction measures.

5.4 Who Bears the Costs

5.4.1 Allocation of Costs between Government and Industry

One of the key aims of the proposals set out in the EU White Paper is to transfer the costs currently being incurred by Competent Authorities in the various Member States to industry. As noted in Section 2.1, the Commission review of chemicals regulation considered that the current allocation of costs between public authorities and industry was inappropriate. Thus, as one would expect, most of the costs arising under the EU White Paper would fall on industry rather than on Government bodies. Table 5.3 provides a summary of the proportion of the costs estimated under each scenario that would fall on the public versus the private sector.

Scenario	Total PV Costs	Costs to CAs	Costs to Industry	SMEs
Base Legislation	107	13 (12%)	94 (88%)	Expected to be minor
UK Chemicals	197	13 (6%)	184 (94%)	Likely to contribute to hazard data and RA and RRS costs
EU White Paper	620	8 (1%)	612 (99%)	Likely to have significant impacts on SMEs across a range of sectors from testing, RA, RRS and downstream user requirements

5.4.2 Impacts on SMEs

Table 5.3 also highlights where SMEs may incur a large share of the estimated costs. As Section 1.2 notes, 96% of EU chemicals companies are SMEs. Consultation with industry associations indicates that SMEs in the UK play an active role in the development of new chemicals, particularly in the field of specialty chemicals. New

specialty chemicals arise more frequently than new bulk chemicals, though the volumes marketed will be smaller. Costs (and benefits) associated with new chemicals under the strategy may therefore fall disproportionately on SMEs.

SMEs may also be disproportionately affected by the requirements placed by the EU White Paper on downstream users of chemicals. As Table 1.3 (in Section 1.2) shows, SMEs constitute a large proportion of companies amongst some of the key downstream user sectors. Thus, a large share of the estimated £44 million in testing and risk assessment requirements for downstream users may be incurred by SMEs (or their trade associations). Consultation with industry has indicated that such companies would face considerable difficulties in carrying out any testing and risk assessment required by the White Paper Strategy.

The role of SMEs in relation to other existing chemicals is harder to determine. Undoubtedly, SMEs manufacture existing chemicals covered by each of the options, and indeed SMEs have played a role in the ICCA programme. However, it is not possible to identify how many of the existing chemicals covered by each of the options is manufactured by SMEs and thus what proportion of the associated costs they would bear. The allocation of costs also depends upon how the provisions relating to existing chemicals are implemented. If a consortium approach, similar to that adopted for the ICCA programme, is used it might be expected that the costs would be shared between SMEs and other chemical companies according to their resources and/or the profits derived from different chemicals. Should such an approach prove impossible, for example because of concerns over commercial confidentiality, then the burden on SMEs could be greater.

Table 5.1: Key Assumptions and Associated Cost Estimates by Procedure and Scenario						
Procedure	Scenario	New or Existing Substances	Cost Item	Number of Chemicals		Cost Estimates¹ (£ per chemical)
				EU	UK	
Registration	Base Legislation	New Substances	Preparation of Base Set data, testing and risk assessment	8000	1300	£ 57,000 - £ 85,000
	UK Chemicals Strategy	New Substances	Preparation of Base Set data, testing and risk assessment	n/a	1300	£ 57,000 - £ 85,000
		Existing Substances	Data gathering for priority chemicals under Stakeholder Forum	n/a	50	£ 500,000 ³
			Hazard data for all commercially produced chemicals (no testing required)	n/a	20,000	£ 5,000
	EU White Paper	New Substances	Preparation of Base Set data (Annex VIIa)	4000	650	£ 57,000 - £ 85,000
		Existing Substances	Dossiers for registration of all chemicals >1t (constant across all quantities relates to in vitro testing, preliminary risk assessment and risk reduction as required)	25,000 (assumes data already exists for 5,000)	3,000 (assumes UK industry does 12%)	£ 25,000
Testing	Base Legislation	Existing Substances	ICCA development of Base Set data equivalent	1500	300	£ 57,000 - £ 85,000
	UK Chemicals Strategy	Existing Substances	ICCA development of Base Set data equivalent	1500	300	£ 57,000 - 85,000
	EU White Paper	Existing Substances	Base Set data required for testing and evaluation of quantity 10-100t	5,300	1060	£ 57,000 - £ 85,000
			Base Set and Level 1 testing for 100-1000t (assumes data exist for 500 chemicals)	2,000	400	£ 210,000 - £ 300,000
			Base Set, Level 1 & 2 testing for >1000t (assumes data exist for 500 chemicals)	2,000	400	£ 412,000 - £ 800,000
			Testing by Downstream Users	3000	600	£ 50,000

Procedure	Scenario	New or Existing Substances	Cost Item	Number of Chemicals		Cost Estimates ¹ (£ per chemical)
				EU	UK	
Evaluation	Base Legislation	Existing Substances	Competent Authority review of ICCA Data	1500	300	£ 8,500 ²
	UK Chemicals Strategy	Existing Substances	Competent Authority review of ICCA Data	1500	300	£ 8,500 ²
	EU White Paper	New and Existing Substances	Competent Authority spot check of industry data (dossiers and other data)	25000+	130 new (1 in 10) 300 existing (10% of 12%)	£ 8,500 ²
Notification and Authorisation	Base Legislation	New Substances	Competent Authority notification charges for <1 tonne	4000	1300	£ 2,000 ²
			Competent Authority notification charges for >1 tonne	4000	1300	£ 8,500 ²
		Existing Substances	HSE preparation of ESR Risk Assessments	N/a	80	£ 52,000
			EA preparation of ESR Risk Assessments	N/a	80	£ 75,000
			Competent Authority Review of non-UK ESR Risk Assessments	400	300	£ 8,500 ²
			Competent Authority preparation of Risk Reduction Strategies	320	65	£ 50,000
	Competent Authority Review of non-UK ESR Risk Reduction Strategies		320	260	£ 7,000	
	UK Chemicals Strategy	New Substances	HSE and EA charges for <1 tonne	4000	1300	£ 2,000 ²
			HSE and EA charges for >1 tonne	4000	1300	£ 8,500 ²
		Existing Substances	HSE Preparation of ESR Risk Assessments	N/a	80	£ 52,000
			EA Preparation of ESR Risk Assessments	N/a	80	£ 50,000
			Competent Authority Review of non-UK ESR Risk Assessments	400	300	£ 8,500 ²
			Competent Authority preparation of Risk Reduction Strategies (80% of RAs)	320	65	£ 50,000
			Competent Authority Review of non-UK ESR Risk Reduction Strategies	320	260	£ 7,000 ²
			Industry preparation of risk assessments for Stakeholder Forum	N/a	50	£ 50,000
Industry preparation of risk reduction strategies for Stakeholder Forum (80% RAs)			N/a	42	£ 50,000	

Procedure	Scenario	New or Existing Substances	Cost Item	Number of Chemicals		Cost Estimates ¹
				EU	UK	(£ per chemical)
Notification and Authorisation	EU White Paper	New Substances Existing Substances	Risk assessments for unintentional downstream uses of chemicals of concern (assumes 3,000 such uses of concern)	3,000	600 (20% of uses)	£ 50,000 (assumes most data exist)
			Additional testing for chemicals of concern where these chemicals (out of 1,400 anticipated) are not covered by other testing and evaluation requirements	500	100 (20%)	£ 275,000 to £ 800,000 (to allow for Level 1 and 2 testing)
			Targeted risk assessments for chemicals of concern	1,400	280	£ 25,000
			Targeted risk reduction strategies for chemicals of concern	1,400	280	£ 25,000
			Competent Authority reviews of risk assessments and risk reduction proposals as part of authorisation (12% of total EU)	1,400	168	£ 10,000
			Competent Authority reviews of downstream users' assessments	3,000	600	£ 8,500 ²
			Competent Authority reviews of downstream users' assessments	3,000	600	£ 8,500 ²
<p>1 Ranges are given for those costs where different estimates are given by the Chemicals Industries Association, DETR (1999) and European Commission (2001).</p> <p>2 Where figures are given for Competent Authority Reviews, these are based on HSE cost data. It is assumed that other CA costs are equivalent to HSE's costs.</p> <p>3 Assumes that Base Set data and Level 1 testing will be required in all cases and Level 2 testing will be required for 50% of chemicals as per EHI (2001).</p>						

6. RESULTS OF CONSULTATION

6.1 Introduction

For the purposes of carrying out this RIA, consultation has been undertaken with:

- trade associations involved in the ‘downstream’ use of chemicals;
- trade associations and companies involved in the manufacture and supply of chemicals; and
- UK Government departments and agencies¹¹.

A list of organisations contacted is provided as Annex 1. A list of the types of questions asked of these consultees is provided in Annex 2.

It should be noted that there were considerable differences in interpretation of the EU Strategy’s requirements between different consultees and their responses reflect these differences.

6.2 Manufacturers and Suppliers of Chemicals

Testing

Concern has been expressed that the number of chemicals potentially covered by the Strategy could actually be higher than the number indicated in the White Paper: if resulting legislation for registration applies to *pre-manufacture* chemicals rather than *pre-market* chemicals the number covered could be between three or four times that stated (i.e. 90,000 to 120,000 as opposed to 30,000).

It has been suggested that, rather than non-EU companies undertaking testing of chemicals imported into the EU, responsibility will be placed upon the EU-based companies importing the substance. The costs given for undertaking testing according to the White Paper are considered to be underestimates and additionally, the EU does not have the capacity for undertaking testing on so many substances, leading to testing being undertaken outside the EU.

In terms of allocation of responsibility, the model used under the ICCA HPV programme¹² would seem to be a suitable model for hazard testing. However, in terms of exposure testing and risk assessment, confidentiality of data is likely to be more of an issue (since details will be required on how a substance is used).

Companies would be expected to face significant issues relating to the lack of available resources and technical expertise for undertaking the required hazard assessment,

¹¹ Responses have been incorporated into the scenarios developed for this Partial RIA and are not specifically described below.

¹² With the burden shared according to production volume (or other mutually agreeable system).

exposure testing, risk assessment and notification work required under the EU proposals. This is particularly true for specialty chemicals, where around half of companies are SMEs. They anticipate having to buy in expert support to carry out risk assessments, with dedicated staff being needed to manage risk assessment and risk reduction projects. It is unlikely that such costs could only be supported across all chemicals, with this potentially resulting in a reduction in the number of chemicals available to certain processes. This impact could affect the more benign chemicals, as well as those posing risks to health and the environment.

Concern has also been expressed that specific proportionate data sharing provisions should be included in the proposals, rather than encouragement of companies to share data.

However, the increased thresholds for testing will benefit the EU chemical industry in terms of stimulating innovation.

Risk Assessment and Downstream Users

Industry suggests that the White Paper gives little regard to the considerable existing legislation in place for controlling risks to health and the environment. The costs of undertaking the required risk assessments will vary according to the level of detail that is required under any legislation that is introduced. However, it will generally introduce significantly higher costs, which may not be viable for smaller companies.

In many cases there will be uses of chemicals where the profit margins for either the producers or users will be too small to justify carrying out a risk assessment of that use. Again, this could potentially lead to the loss of many uses of chemicals.

In terms of benefits, where risk assessments are more targeted, this will generally tend to make them cheaper, faster and more pragmatic than those conducted at present under Regulation 793/93.

The Authorisation Procedure

There have been concerns expressed about the authorisation procedure since it effectively introduces a positive list of uses for chemicals. This is along similar lines to regimes such as that for pesticides (though with potentially far greater number of uses per substance) which has, thus far, not produced a quicker means of chemical regulation.

6.3 Downstream Users of Chemicals

6.3.1 Metal Finishing and Surface Treatment

The Metal Finishing Association has consulted widely with its members on the implications of the proposed EU Strategy. They have strongly stated that the Strategy would place unreasonable demands upon the industry: given that over 50% of its

members employ 10 people or fewer, companies are not considered to have the financial resources to carry out the proposed testing and assessment procedures.

Several companies reported that the Strategy would impose costs that would stifle many new projects and products. Several are reported to already be struggling to meet the requirements of current legislation (such as COSHH). Generally, for SMEs, companies will not have the expertise to undertake the required testing and assessment, with the outcome that they would either have to employ an extra person to manage the new requirements or use independent consultants. Neither of these options is considered viable for many of the companies and it was indicated that there is no more scope for these types of costs to be passed on to consumers. The Strategy, could, therefore, result in the closure of many of these companies with a shift in production to countries where legislation is less stringent.

Some companies indicated that all substances are used in the way intended by the manufacturer and so no extra testing would be required, although they would have to obtain and review revised SDSs and revise existing COSHH assessments¹³.

Other companies stated that chemicals are not always used as intended¹⁴ and a requirement for risk assessment on new chemicals introduced into metal finishing would stifle innovation (i.e. modification and development of processes could be limited).

Concerns have also been raised in relation to the comparison of costs and benefits in the Strategy: the White Paper states that the benefits will outweigh the costs even if a small reduction in the costs associated with allergies that occur in the EU. However, the White Paper does not provide any indication as to the proportion of those allergies that are caused by chemicals.

Companies have also stated that there would be problems associated with assessing risks when products are mixed and broken down by reactions (as is often the case with chemicals used in metal finishing).

6.3.2 Paper Chemicals

The Paper Chemicals Association would welcome the Strategy if it leads to greater protection of the public, consumers and the environment. However, they indicate that the required testing would make the Strategy impracticable, raising the fact that there are 100,000 chemicals on the EINECS list, with a further 1000 times this number of preparations and an equivalent number of polymeric chemicals. They indicate that the Strategy may not be clear in terms of whether 'chemicals' that require testing under the

¹³ One company suggested that a low estimate of such costs could be £30 per substance. Of the companies providing information, the number of substances used is between around 40 and several hundred, making costs of the order of thousands to possibly tens of thousands of pounds (assuming that all chemicals are used as intended by the manufacturer).

¹⁴ Companies reportedly tend to use proprietary chemicals as intended, as well as general chemicals which may be used in a variety of ways.

Strategy include preparations, chemical intermediates, polymeric chemicals and chemical products.

They estimate that the costs of undertaking the testing, if the wider interpretation of 'chemicals' is used, could be as much as £60 trillion, based upon testing costs of £300,000 per chemical, with 2000 x 100,000 items requiring testing.

6.3.3 Rubber Manufacture

The British Rubber Manufacturers' Association has raised the concern that the overall Strategy introduces a shift towards regulation of chemicals in terms of their hazards rather than the risks, citing the risk assessment and management process under the Existing Substances Regulation as a scientifically sound approach.

They indicate that SMEs lack the necessary expertise to undertake exposure testing, risk assessment and notification and thus the associated costs would have serious consequences for the competitiveness of the industry. They estimate that there are around 300 chemicals currently used by about 300 companies in the sector, 90% of which are SMEs. They also indicate that the costs of undertaking risk assessment for one chemical used in the sector could be of the order of £50,000 to £100,000.

6.3.4 Adhesives and Sealants

The British Adhesives and Sealants Association indicated that the proposals are likely to force smaller companies out of business, particularly in terms of acquiring adequate risk data for proposed new applications of chemicals. They also expressed concerns regarding the intellectual property rights on such information.

6.3.5 Coatings

The British Coatings Federation has provided qualitative views on the Strategy set out in the White Paper. They indicate that the requirements for data on substances are well thought out but that there exists considerable uncertainty in relation to the implications for downstream users of chemicals (cost implications might potentially be significant).

The BCF report that the implications for downstream users (such as producers of coatings) will depend upon factors such as the following:

- the definition of use: if an 'intended' use of a chemicals were to be specified as, for example, 'use in paints', there would be considerably fewer implications for risk assessment than if intended uses were required to be specified for various types of paints used in various applications. They also suggest that intended uses should cover *all* existing uses of a chemical and further that the concept of having intended uses limits the potential for innovative uses of chemicals;

- there is insufficient elaboration in the White Paper as to the criteria by which “safe” use of a chemical is judged¹⁵;
- it is uncertain how the precautionary principle will be applied in implementing the Strategy;
- there is considerable uncertainty in relation to the level of data that would be required for risk assessments conducted under the Strategy (which would impact upon the associated costs);
- tests on hazard information will only be undertaken by chemical manufacturers (or downstream users for non-intended uses) where the costs will be covered by future sales. Low margin and low volume chemicals would then be susceptible to being abandoned¹⁶; and
- the above factors would mean that the range of chemicals used is regulated (in practice) more by the economic implications of testing rather than the risks associated with their use.

¹⁵ The White Paper requires that “Industry should also ensure that only chemicals that are safe for the intended uses are produced and/or placed on the market.”

¹⁶ This has reportedly occurred with some substances under legislation such as the Plant Protection Products Directive, Biocidal Products Directive and food contact materials legislation.

7. COMPLIANCE ISSUES

Based on the consultation undertaken for this partial RIA, a number of issues relating to possible non-compliance with the EU White Paper strategy have been identified. However, given that there remain considerable uncertainties about how the EU proposals will translate into any future legislation, these issues are only indicative of potential problems.

Firstly, there are many questions over the ability of manufacturers to meet the full testing, risk assessment and risk management requirements within the time frame allowed. This is of particular concern for SMEs. There is also concern that insufficient consideration has been given to the procedures by which the costs of chemicals testing and risk assessment could be shared amongst companies that benefit from such work. If there is no robust system, companies could potentially benefit from such information without contributing to the cost of its generation (in other words 'free rider' problems could arise).

Secondly, several sources have indicated that downstream users which use chemicals for applications other than those which are intended by the manufacturer are unlikely to notify such uses to the authorities. Not only would such notification impose potential obligations upon that company to undertake testing but it would also potentially allow other companies access to commercially sensitive information.

Attention has also been drawn to the current system for collection of data under the Existing Substances Regulation: companies are likely to hold more data on substances than has been submitted to the authorities for inclusion in the IUCLID database (having not submitted data possibly because of the resource implications of doing so). It has been suggested that the low level of data submission is a result of inappropriate enforcement mechanisms. The system proposed under the EU White Paper could potentially have the same problems if the compliance regime is insufficient. Furthermore, issues arise over enforcement of the requirements on importers of chemicals to the EU.

8. SUMMARY

The aim of this partial RIA is to:

- identify the potential costs (including costs to SMEs) and benefits for the UK of the proposals in the EU White Paper and of alternative options including non-legislative ones; and
- to inform the UK position for negotiations of Council Conclusions on the White Paper.

Three different scenarios were considered in order to fully understand the implications of the EU White Paper. The first of these acts as the baseline for the analysis, and reflects the existing legislative process together with voluntary commitments by industry. The second scenario reflects the requirements of the UK Chemicals Strategy (DETR, 1999), while the third scenario represents requirements under the EU Strategy as set out in the White Paper (although several assumptions have had to be made as to implementation in practice). The key findings of the partial RIA are as follows:

1. There are considerable differences in interpretation of the White Paper requirements between those consulted for this RIA. This has introduced uncertainty into the analysis findings.
2. Under the EU White Paper, the maximum potential benefits from reduction in the risks of chemicals arising from the provision of additional information and restrictions on substances of concern could include:
 - reduced costs of occupational injuries and fatalities amounting to £64-129 million over 10 years;
 - reduced costs of occupational asthma and dermatitis totalling £580 million to £1.2 billion over 10 years; and
 - unknown benefits arising from reduced costs associated with occupational cancer from non-occupational exposure, and environmental damage associated with chemicals.

However, a number of caveats must be placed on these figures related to the ability to achieve such reductions and what economic costs are covered by the figures. As a result, it is not possible to determine the incremental benefits provided by the EU White Paper proposals.

3. Additional benefits will arise to the chemical industry from the increased threshold for notification of new substances. This is estimated at £34 million in present value terms (at 6% over the 20 years).
4. The estimated total present value costs of the scenarios are as follows (at 6% over 20 years):

- Base Legislation: £ 107 million
- UK Chemicals Strategy: £ 197 million
- EU White Paper: £ 620 million

5. The EU White Paper results in additional costs of around £513 million over the Base Legislation scenario and £423 million over the UK Chemicals Strategy. These are costs to the UK alone.
6. Making a rather simplistic comparison of the above figures to the maximum worker-related health benefits outlined in Section 4, the additional costs associated with UK Chemicals Strategy scenario may be justified by a 15% reduction in occupational asthma and dermatitis if risk reduction is costless - an unlikely outcome. Whether a balance will be achieved between costs and benefits will depend not only on the costs or risk reduction but also on the additional benefits that would arise from reductions in health effects across the general public together with environmental benefits and greater public confidence.

The case may be more marginal for the EU White Paper, however, with a 70% reduction in the cases of occupational asthma and dermatitis - a highly optimistic assumption - being required to offset the estimated scenario costs alone. Thus, significant further reductions in health effects to the general public, together with environmental benefits and greater public confidence would need to be achieved in order to off-set the additional costs of implementing this strategy and the associated risk reduction measures.

7. Under the Base Legislation scenario, Government in the form of the Competent Authorities is predicted as bearing 12% of the total costs. This reduces to 9% under the UK Chemicals Strategy, as industry picks up a greater share of responsibility. However, the transfer of costs is more dramatic under the EU White Paper, with Competent Authorities bearing only 1% of total present value costs. Of particular concern with the latter scenario though is the impact that it may have on SMEs, as they are likely to constitute a higher proportion of the downstream users affected.
8. There are likely to be significant compliance issues under the EU White Paper requirements (although the detailed implementation has yet to be determined). In particular, there are questions over the ability of manufacturers to meet the full testing, risk assessment and risk management requirements within the time frame allowed. This is a particular concern for SMEs. There are also questions over the sharing of testing and risk assessment responsibilities between companies.

It is unclear how the registration, data collection and testing activities required of downstream users can be enforced, particularly in light of the problems which have risen under the Existing Substances Regulation. For example, what regulatory authorities will have responsibility for ensuring that a chemical is registered and assessed, and that all uses (envisaged and non-envisaged) have been assessed as required. Furthermore, issues arise over enforcement of the requirements on importers of chemicals to the EU.

ANNEX 1

ORGANISATIONS CONTACTED

A1. ORGANISATIONS CONTACTED

A1.1 Chemicals Trade Associations

British Chemical Distributors and Traders Association
British Association of Chemical Specialities
Chemical Industries Association

A1.2 Downstream Trade Associations

British Coatings Federation
British Surface Treatment Suppliers Association
British Leather Confederation
British Lubricants Federation
British Plastics Federation
British Rubber Manufacturers Association
British Adhesives and Sealants Association
Confederation of British Wool Textiles
Cosmetic Toiletry and Perfumery Assn
Federation of Small Businesses
Federation of the Electronics Industry
Institute of Metal Finishing
Metal Finishing Association
Paper Federation of Great Britain
Paper Chemicals Association
Printed Circuit Interconnection Federation
Soap and Detergent Association

A1.3 Government Departments

Department of the Environment, Transport and the Regions
Department of Trade and Industry
(Chemicals Directorate, Small Business Service)
European Chemicals Bureau
Environment Agency
Health and Safety Executive
(Chemical Supply Management Unit, Industrial Chemicals Unit)
Pesticides Safety Directorate
Scottish Environment Protection Agency

ANNEX 2

TYPES OF QUESTIONS ASKED OF CONSULTEES

A2. TYPES OF QUESTIONS ASKED OF CONSULTEES

A2.1 UK Regulators

New Substances

1. How many notifications of new substances are received each year?
2. How many of these are from non-UK based companies?
3. Do you have any views on the number received from SMEs as opposed to major chemical companies?
4. How many notifications concern substances marketed in quantities below 1 tonne?
5. How many substances initially marketed in quantities below one tonne are subsequently produced in amounts over one tonne?
6. What work does the unit typically carry out to review notifications?
7. How much time does this typically take (in person-hours)?
8. How frequently are notifications returned to manufacturers for further data/improved risk assessment?
9. Are certain types of applications/manufacturers more likely to require additional information?
10. What fees are levied for notification of new substances and what determines the level of fees?
11. How frequently and by how much are fees increased?
12. Do fees cover the full costs of [Competent Authority]'s work, including training and any investment?

Existing Substances

13. What work is carried out by the [Competent Authority] in relation to the assessment of existing substances?
14. What are the costs of this work and how is it funded?
15. What is your envisaged role in reviewing data submitted by industry under (a) the ICCA HPV Chemicals initiative, and (b) the UK Chemicals Strategy? What are the associated costs of these reviews?

Resources

16. Do you have sufficient resources to deal with a significant increase in the number of substances to be assessed?
17. If not, what would be the barriers to obtaining sufficient resources (e.g. cost, availability of qualified staff, facilities, etc)?

Other

18. Do you have any other cost or resource related concerns arising from the EU proposals? How does the [Competent Authority] view these proposals?

A2.2 Chemicals Manufacturers

General Data

1. Is the Commission's figure of 30,000 substances likely to be a reasonable indicator of the number that will be affected, or is it more likely to be an underestimate or overestimate.
2. Do you have any feel for what proportion of these substances are likely to be covered by existing legislation, e.g. sector specific legislation or broader measures such as the Water Framework Directive and IPPC?
3. Can you provide an indication of the number of new and existing substances produced in the UK, with this apportioned between large manufacturers and SMEs. If possible, we would like this data to be provided separately for CMR, POPs and other substances.
4. Around 30% of new substances are authorised through the UK. Would you expect this type of figure to also hold for Existing Substances under the new Strategy?

Testing and Risk Assessment Related Data

5. Will the increase in thresholds for notification and testing of new substances and the extended conditions for exposure scenarios and research and development result in significant cost savings? What proportion of new substances are likely to benefit from these changes? Will this aid competitiveness?
6. What thoughts do you have on how companies would allocate responsibility for undertaking the required testing, etc.? Does the ICCA voluntary programme provide a good model for how this might be done? If so, how are responsibility and costs allocated across companies? What proportion of the SIDS are being produced by UK companies?
7. Is it possible to provide estimates of the costs associated with the various testing requirements (base set, Level 1, Level 2) based on current experience? Do the Commission's estimates provide a reasonable basis for estimating the costs to industry?
8. How do these compare to the costs of preparing 'initial risk assessments' as proposed by CEFIC to the commission (e.g. the type of assessments that are carried out for substances on the OSPAR list)?
9. Do you agree with the estimate that 80% of substances would require only a preliminary risk assessment, with the remainder then going to registration, evaluation and authorisation?

10. What savings/costs might arise from the adoption of a more targeted risk assessment approach (in place of the current comprehensive risk assessments required under 793/93)?

Registration, Evaluation and Authorisation

11. What comments do you have on the proposed registration, evaluation and authorisation procedures?
12. What impacts are the requirements for industry to produce socio-economic justifications for substances of very high concern likely to have (under Steps 1 and 2)?
13. Will the revised system offer real advantages over the current system with regard to the ability to de-restrict certain uses of substances following the introduction of adequate safety measures or technological developments?

Downstream Users

14. Do you believe that there will be significant numbers of uses falling under actions 5 a, b and c, requiring assessments to be produced by downstream users?
15. What is your interpretation of the requirements on downstream users with regard to exposure, testing, risk assessment and notification?
16. Can you provide an indication as to the possible number of companies affected by the requirements placed on downstream users, e.g. the number of formulators of preparations?

Timetable

17. Can the proposed timetable be met?

Classification and Labelling

18. What are your views on the provisions concerning classification and labelling?

A2.3 Downstream Users of Chemicals

1. What are your views on the feasibility for your members of undertaking exposure testing, risk assessment and notification as required by the Strategy?
2. What costs could be expected for your members in fulfilling these requirements?
3. Can you provide any indications as to the number of chemicals that are used by your members and the number of companies potentially affected by the requirements on downstream users?

ANNEX 3

KEY ASSUMPTIONS AND SENSITIVITY ANALYSIS

A3. KEY ASSUMPTIONS AND SENSITIVITY ANALYSIS

A3.1 Introduction

In specifying the types of activities that would be undertaken under each of the scenarios, a number of assumptions had to be made. To the degree possible, these were based on the data collected from those consulted during the study, where this related to actual experience and/or informed judgement. In other cases, the assumptions were based on our own judgement concerning the effect of different requirements/activities on industry and Competent Authorities.

The key assumptions in terms of their potential impact on the reliability of the analysis results and the comparison between scenarios are presented below.

A3.2 UK Levels of Effort

For a number of the defined activities, a decision had to be made as to the level of effort that would be put into them by industry or be required of Competent Authorities. The figures presented in the main report represent our best guesses as to the level of effort, based either on discussions with industry or a reasonable interpretation of the various documentation produced by the DETR and the Commission.

In general, it is assumed that UK industry will take responsibility for some 20% of chemicals requiring testing and assessment activities, in line with their commitments under the ICCA programme. For the Base Legislation and UK Chemicals Strategy scenarios, it is assumed that UK authorities would also undertake evaluation activities of a similar magnitude. Under the EU White Paper strategy, it is assumed that UK industry and Competent Authorities are responsible for 12% of chemicals, in line with the UK industry's share of the EU industry's turnover.

The impact of changing these assumptions on the present value cost estimates on the various cost items can be seen from examination of Table A3.1.

Scenario	Cost Item	Best	Low	High
Base Legislation	ICCA base set data costs	20.2	19.1	20.2
	Competent Authority review of ICCA data	1.5	0.9	1.5
UK Chemicals Strategy	ICCA base set data costs	21.5	21.1	21.5
	Competent Authority review of ICCA data	1.5	0.9	1.5
EU White Paper	Dossiers	52.2	52.2	56.4
	Testing of existing substances and unintentional uses	463.2	278.1	515.0
	Evaluation spot checks	2.5	1.5	4.2
	Additional testing, risk assessments and risk reduction activities	68.2	41.6	128.8
% Best estimate costs with change in level of effort		100%	66%	119%

Under the low estimates, it is assumed that 12% of chemicals fall to UK industry and Competent Authorities, while the high estimates assume that 20% fall to the UK. As can be seen from the table, the most dramatic differences arise from variations in assumptions concerning the proportion of testing and risk assessment related work that is allocated to UK industry. The variations in assumption concerning the number of chemicals that UK Competent Authorities take responsibility has only a small effect on overall costs (although these may be significant to the budgets of the bodies affected).

Whether a low or high figure has been adopted for the 'best' options can be determined by identifying those cost items for which the estimated costs are the same.

A3.3 Stakeholder Forum Chemicals and Related Hazard Data

A key assumption made for the UK Chemicals Strategy scenario concerns the number of chemicals which UK industry will have to provide hazard data for and then the costs of so doing. For the main assessment, we have assumed that UK industry will have to provide hazard data for 20,000 chemicals at a cost of £5,000 each. This may well represent an over-estimate of the level of effort required by UK industry, as such data can be expected to already exist or be produced by industry elsewhere in response to on-going regulatory and interest group pressure. As a sensitivity analysis, we have examined the difference in costs that would arise from UK industry having to prepare such data for 10,000 chemicals, but again at a cost of £5,000 per chemical. This effectively results in the halving of costs as follows:

- 20,000 chemicals: £62 million;
- 10,000 chemicals: £31 million.

This difference is significant given that the 'best' estimates of total costs for this scenario are around £175 million. Should the figure of 10,000 chemicals be more appropriate, this would reduce the total present value costs of this scenario by almost 18%.

Related to the above is the assumption made concerning the number of risk assessments that will have to be produced by industry in response to requests from the Stakeholder Forum. It has been assumed that data collection (including base set, and some Level 1 and Level 2 testing), risk assessments and risk reduction strategies will be required for 50 chemicals (with the need to prepare risk reduction strategies arising for 80% of these). This may be an over-or under-estimate. For sensitivity purposes, this figure has been reduced to 25. Again this halves the costs as follows:

- 50 chemicals: £27 million;
- 25 chemicals: £13.5 million.

This difference of over £13 million is not that significant on its own (at around 7% of total scenario costs), but when added to the assumption concerning the expenditure that will be required by industry on producing hazard data it may result in total costs being over-estimated by almost 25%. In relative terms, this may be penalising the UK Chemicals Strategy scenario in comparison to the other scenarios.

A3.4 Testing Costs and Requirements

Significantly different estimates of the costs of undertaking the various testing requirements were found from the three main sources of data [industry consultation, EU White Paper and Testing Report (IEH, 2001)]. As can be seen from Table A3.2, those contained in the EU White Paper are lower than those quoted by other sources.

Test Level	EU White Paper	Industry Estimates	IEH Testing Report
Base set data	£ 57,000	£ 85,000	£ 75,000
Level 1 testing	£153,000	£200,000	£ 187,000
Level 2 testing	£200,000	£500,000+	£ 812,000
Total for Base set, Levels 1 & 2	£410,000	£785,000+	£1,075,000

As would be expected, the set of estimates adopted has an impact on the estimated costs for each of the three scenarios. This is illustrated by Table A3.3 (which also indicates how changes in discount rates from a government rate to an industry rate affect the estimated present value costs). As the industry cost estimates reflect the views of UK consultees, these have been used as providing the best source for the main set of figures provided in this report (although a government discount rate has been adopted as recommended in the Guide to RIA).

Scenario	Procedure	EU White Paper		Industry Data		Testing Report	
		6%	8%	6%	8%	6%	8%
Base Legislation	Registration	46.2	40.1	68.9	59.8	60.8	52.7
	Testing	11.5	10.3	17.2	15.3	15.1	13.5
	Evaluation	1.5	1.3	1.5	1.3	1.5	1.3
	Notification and Authorisation	19.6	17.0	19.6	17.0	19.6	17.0
	PV Total	78.8	68.6	107.1	93.4	97.0	84.5
	% EU Figures	100%		136%		123%	
UK Chemicals Strategy	Registration	121.2	106.5	154.2	136.2	146.1	129.2
	Testing	12.3	11.2	18.3	16.7	16.2	14.7
	Evaluation	1.5	1.3	1.5	1.3	1.5	1.3
	Notification and Authorisation	23.3	20.4	23.3	20.4	23.3	20.4
	PV Total	158.2	139.4	197.3	174.6	187.0	165.6
	% EU Figures	100%		125%		118%	
EU White Paper	Registration	75.4	68.2	86.7	78.1	82.6	74.6
	Testing	283.2	268.6	463.2	440.7	551.7	526.7
	Evaluation	2.5	2.2	2.5	2.2	2.5	2.2
	Notification and Authorisation	54.0	48.0	68.2	60.3	87.1	76.7
	PV Total	415.1	387.0	620.5	581.2	723.9	680.2
	% EU Figures	100%		149%		175%	

* Note that differences may arise owing to rounding errors.

As can be seen from Table A3.3, assumptions concerning testing costs are most important to total estimated costs for the EU White Paper scenario. This is only to be expected given the increased requirements for Level 1 and Level 2 testing. It would appear that the costs of these further testing requirements are the most subject to variability across chemicals, with this introducing considerable uncertainty into the analysis conclusions.

We believe that assumptions concerning the number of substances requiring the different levels of testing are fairly robust as they are based on the number of chemicals produced for each of the quantity thresholds and information on the number of chemicals for which test data currently exist.

The assumptions concerning the number that may require additional testing (as part of Notification and Authorisation), however, are guesstimates. Of the 1,400 chemicals that are expected to go through the EU Authorisation procedures, one could expect a significant number of these to have been tested to Level 1 or Level 2 requirements already. Our assumption that 500 chemicals would require further testing is based on the fact that the majority of chemicals are produced in quantities of less than 10 tonnes and thus would require further testing at this stage. This assumption is highly uncertain, however. Increasing this figure to 1000 chemicals would add an additional £32 million to the costs of UK industry in undertaking the additional testing (assuming that the UK covers 200 or 20% of the chemicals). This would add almost 50% to the costs estimated here for Notification and Authorisation under the EU White Paper scenario.

A3.5 Downstream User Requirements

A further key uncertainty affecting the estimates produced for the EU White Paper scenario concerns the requirements that will actually be placed on downstream users. From the details given in the White Paper, it is difficult to determine how such requirements would be implemented and, hence, the likely number of chemicals and 'unintentional' uses that may be affected. In addition, it is difficult to predict how industry might respond to such requirements, for example, by ceasing use of some specialist chemicals, shifting production to non-EU facilities, failing to comply with requirements, etc. As highlighted by the consultation with trade associations, many thousands of chemicals could be affected with numerous (tens to hundreds of) unintentional uses associated with each. Small to medium sized companies in particular are likely to find difficulties in fulfilling onerous testing, risk assessment and risk reduction requirements.

A figure of 3,000 unintentional uses (with UK industry responsible for 12% of these) has been assumed for the main estimates, with this increased to 10,000 for the high estimate sensitivity analysis (with UK industry taking responsibility for 2,000 or 20% of such uses). As might be expected, varying the number of unintentional uses has a significant impact on the estimated Notification and Authorisation costs for the EU White Paper.

The increase in uses that must be addressed is estimated here as adding a further £50 million to the costs faced by UK industry (with these increasing from around £22 million to £74 million assuming they take responsibility for 20% of the assessments required for such uses).

A3.6 Summary

A range of other assumptions has been made in order to prepare the cost estimates. However, reasonable variations in these do not have significant impacts on the estimates presented in the main report.

In order to highlight the cumulative effect of the various assumptions, the effect of adopting either low or high estimates across all aspects of the scenarios are reported in Table A3.4, using industry cost data (and assuming a 6% discount rate). As can be seen from this table, assuming the high figures are correct would add some £120 million (or 20%) to the total estimated costs. On the other hand, assuming the low figures are correct suggests that the ‘best’ estimates given in the main report over-estimate costs by some £213 million or by some 50%. In our view, however, it is more likely that the ‘best’ estimates represent under-estimates than over-estimates.

Procedure	Scenario	Best	Low	High
Registration	Base Legislation	68.9	68.9	68.9
	UK Chemicals Strategy	154.2	111.5	209.2
	EU White Paper	86.7	86.7	90.9
Testing	Base Legislation	17.1	16.2	17.1
	UK Chemicals Strategy	18.3	17.9	19.1
	EU White Paper	463.2	278.1	515.0
Evaluation	Base Legislation	1.5	0.9	1.5
	UK Chemicals Strategy	1.5	0.9	1.5
	EU White Paper	2.5	1.5	4.2
Notification and Authorisation	Base Legislation	19.6	19.6	19.6
	UK Chemicals Strategy	23.3	21.4	23.2
	EU White Paper	68.2	41.6	128.8
Total	Base Legislation	107.1	105.6	107.1
	UK Chemicals Strategy	197.3	151.7	253.0
	EU White Paper	620.5	407.9	738.9

ANNEX 4

REFERENCES

A4. REFERENCES

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